

K032261

AUG 22 2003

## 510(k) Summary

### General Information

Classification	Class II
Trade Name	Trellis™ Reserve Infusion System
Submitter	Bacchus Vascular, Inc. 3110 Coronado Drive Santa Clara, CA 95054  408-980-8300
Contact	Gregory J. Mathison Vice President, Regulatory & Clinical Affairs

### Intended Use

The Trellis™ Reserve Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

### Predicate Devices

Trellis Reserve Infusion System	K023514	Bacchus Vascular, Inc.
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### Device Description

The Trellis Reserve Infusion Catheter enables the physician to isolate a treatment region, infuse a physician-specified fluid, and disperse the fluid by means of oscillation of a Dispersion Wire. The Isolation/Infusion component is a multi-lumen catheter with two compliant balloons at the distal end and infusion holes located between these balloons. When inflated, the compliant balloons isolate a treatment zone to maintain concentration of the infused fluid. The device also has a central through-lumen that is compatible with a 0.035" guidewire. The Dispersion Wire component is a sheathed, shape-set Nitinol cable that provides oscillation when activated. The Dispersion Wire is connected to an integral Oscillation Drive Unit that oscillates the Dispersion Wire within the isolated region to further disperse the infused fluid. If desired by the physician, post procedure aspiration of the isolated area between the occluding balloons may be accomplished through the catheter by using the guidewire lumen.

### Materials

All materials used in the manufacture of the Trellis Reserve are suitable for this use and have been used in numerous previously cleared products.

### Testing Summary

The Trellis Reserve Infusion System was tested in the same manner as the original Trellis Reserve Infusion System (K023514). All components, subassemblies, and/or full devices met the required specifications for the completed tests. The Trellis Reserve was designed under the Bacchus Quality System that is in compliance with 21CFR§820.30.

### Summary of Substantial Equivalence

The Trellis Reserve Infusion System is equivalent to the predicate product, the original Trellis Reserve Infusion System. The indications for use, function, methods of manufacturing, and materials used are substantially equivalent. Bacchus Vascular, Inc. believes the Trellis Reserve Infusion System is substantially equivalent to existing legally marketed devices.



AUG 22 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Bacchus Vascular, Inc.  
c/o Mr. Gregory J. Mathison  
Vice President  
Clinical Affairs, Regulatory Affairs, Quality Assurance  
3110 Coronado Drive  
Santa Clara, CA 95054

Re: K032261  
Trade Name: Trellis Reserve Infusion Catheter  
Regulation Number: 21 CFR 870.1210  
Regulation Name: Continuous flush catheter  
Regulatory Class: II (two)  
Product Code: KRA  
Dated: July 21, 2003  
Received: July 28, 2003

Dear Mr. Mathison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

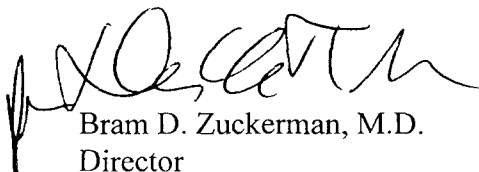
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): This application

Device Name: Trellis Reserve Infusion System

Indications for Use: The Trellis™ Reserve Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over-The-Counter Use ☐

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

  
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number

K032261